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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/072,857  | 02/05/2002  | Mats Allers          | 1774/0K258          | 2347             |
| 7590  | 03/24/2005  |                      | EXAMINER            |                  |
| Robert C. Faber<br>Ostrolenk, Faber, Gerb & Soffen, LLP<br>1180 Avenue of the Americas<br>New York, NY 10036-8403 |             |                      | MAIORINO, ROZ       |                  |
|   |             | ART UNIT             | PAPER NUMBER        | 3763             |

DATE MAILED: 03/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

S/N

|                              |                 |               |  |
|------------------------------|-----------------|---------------|--|
| <b>Office Action Summary</b> | Application No. | Applicant(s)  |  |
|                              | 10/072,857      | ALLERS ET AL. |  |
|                              | Examiner        | Art Unit      |  |
|                              | Roz Maiorino    | 3763          |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 03 January 2005.
- 2a) This action is FINAL.                            2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-68 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) \_\_\_\_\_ is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) 1-68 are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|  | 6) <input type="checkbox"/> Other: _____                                    |

## DETAILED ACTION

### ***Election/Restrictions***

***Applicants election of Group I (claims 1-33) set forth in office action mailed 10/1/04, however with closer examination there seems to be a lot more species than initially given. Hence this second election will clarify the multiple species the examiner did not include in the last office action. Applicant must elect one species from each group.***

This application contains claims directed to the following patentably distinct species of the claimed invention:

#### **Group A**

Speices A-Figure 4

Speices B- Figure 5

Speices C- Figure 6a

Speices D- Figure 68

Speices E- Figure 7

Speices F- Figure 8

#### **Group B**

Speices AA- According to the invention the purpose indicated above is achieved by in a first phase, cf. FIG. 1a, introducing an infusion catheter for infusion of a temperature controlled infusion solution or perfusate into a vein initiating a quick general body hypothermia. In an optional second phase of the invention a second infusion catheter is introduced into an artery of the living being. The second infusion catheter is configured to provide selective temperature control of the brain and infusion of other important substrates and pharmacological compounds into the brain. This accomplishes a quick temperature change in the

brain, involving only a comparatively minor procedure.

Species BB- A further embodiment and possibly a third phase of the invention involves cooling or heating of blood withdrawn from a living being before the blood is recycled to the living being. In this embodiment an extra-corporeal circuit or conduit is established. In one embodiment the extra-corporeal circuit is established between a vein, e.g. a vein in the lower part of the body, and an artery, e.g. the arteria carotis communis, sinister or dexter, arteria subclavia, brachiocephalic trunk, or some other artery that supplies blood to the brain, wherein the temperature of the blood is modified outside the body before the blood is returned to the body through the artery.

Species CC- another embodiment contains the method to reintroduce heated blood to the venous system in order to avoid whole body hypothermia. This embodiment thus allows for heating a first part of the body at the same time as a second part, for example the brain, is cooled. The system for performing this embodiment preferably comprises two separate flow branches or circuits, one for the cooling and one for the heating.

Species DD- Yet another embodiment of the invention involves, in addition to cooling or heating the blood, controlling the oxygenation of the brain and the affected brain hemisphere, i.e. the blood is oxygenated or deoxygenated before it is returned to the body.

Species EE- Varieties of this method further comprises a second hypothermia phase for brain-selective hypothermia, wherein an arterial infusion catheter is inserted into an artery and a second amount of cold solution is infused into the arterial system, to enable a more efficient temperature regulation of the brain.

Species FF- Further embodiments comprise the steps of: percutaneously inserting a temperature sensor in a blood vessel draining blood from the brain; sensing the temperature in the blood of said blood vessel thus providing an indication of the temperature in the brain; adjusting the infusion rate dependent on said sensed temperature for achieving a desired temperature in the brain.

Species GG- In one embodiment the emergency phase may be directly followed by a

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hypothermia phase for maintained hypothermia, comprising the steps of: inserting into a blood vessel an extraction catheter for extraction of blood; inserting an arterial infusion catheter in the vicinity of an artery supplying blood to the brain; establishing a first extra-corporeal blood circuit for cooled blood between said extraction catheter and said arterial infusion catheter via a pumping means and a temperature regulating device capable of cooling extracted blood;

Species HH- A further developed embodiment comprises the steps of: inserting a venous infusion catheter into a vein of the venous system; establishing a second extra-corporeal blood circuit for heated blood between said extraction catheter and said venous infusion catheter via said pumping means and a heating device capable of heating extracted blood; leading a second amount of said extracted blood from said blood vessel via said extraction catheter into said second extra-corporeal blood circuit; heating said second amount of said extracted blood; infusing said heated second amount of extracted blood to said venous system via said venous infusion catheter;

Species II- One embodiment comprises a third hypothermia phase for maintained hypothermia or follows the brain-selective hypothermia phase, the third hypothermia phase comprising the steps of: inserting into a blood vessel an extraction catheter for extraction of blood; inserting an arterial infusion catheter in the vicinity of an artery supplying blood to the brain; establishing a first extra-corporeal blood circuit for cooled blood between said extraction catheter and said arterial infusion catheter via a pumping means and a temperature regulating device capable of cooling extracted blood;

Species JJ- In its most basic form an embodiment of the emergency phase method comprises the steps of: providing a container with a cold infusion solution and an infusion catheter connected to an outlet of said container, said infusion catheter having an infusion solution lumen; percutaneously inserting a distal end of said infusion catheter into a blood vessel that supplies the brain with blood;

Species KK- alternatively phrased, infusing a solution having a first predetermined temperature into a blood vessel supplying said brain hemisphere with blood until said brain hemisphere has reached a predetermined temperature or a predetermined maximum amount of solution has been infused.

Species LL- Other aspects of the invention include: An equipment for brain hypothermia, said equipment comprising, to enable an early and fast inset of the hypothermia: a container with an infusion solution having a first temperature and a venous infusion catheter being connectable to an outlet of said container, said venous infusion catheter having an infusion solution lumen; said venous infusion catheter having a distal end devised to be percutaneously inserted into a peripheral vein;

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a cooling device being configured for cooling the infusion solution to a second temperature lower than said first temperature; wherein the cooling device is configured for cooling the infusion solution to a second temperature in the range of 0-10 degrees Celsius; wherein the cooling device is configured for cooling the infusion solution to a second temperature in the range of 0-4 degrees Celsius;

Species MM- An embodiment for equipment configured use in a brain-selective hypothermia phase comprises an arterial infusion catheter configured to be inserted into an artery and a container with a second amount of cold solution configured to be infused into the arterial system, to enable a more efficient temperature regulation of the brain in a second hypothermia phase for brain-selective hypothermia.

Species NN- n different embodiments this equipment: the arterial infusion catheter is configured to be inserted into a selected peripheral artery; wherein the arterial infusion catheter is configured to be inserted into an arteria radialis; or an arteria brachialis; ] wherein said arterial infusion catheter further is configured to the positioning of a distal tip of said arterial infusion catheter in a selected central artery at the vicinity of a branch artery supplying blood to the brain, wherein said selected central artery is arteria subclavia at the vicinity of arteria carotis, truncus brachiocephalic or ascending aorta.

Species OO- Embodiments may further comprise a device for applying a pressure from the outside of the extremity with the peripheral artery for decreasing peripheral blood circulation. Further embodiments further comprises: a temperature sensor configured to be percutaneously inserted in a blood vessel draining blood from the brain; and being configured to: sensing the temperature in the blood of said blood vessel thus providing an indication of the temperature in the brain; and adjusting the infusion rate dependent on said sensed temperature for achieving a desired temperature in the brain.

Species PP- A further developed embodiment is followed by a third hypothermia phase for maintained hypothermia, and comprises: an extraction catheter being configured to be inserted into a blood vessel for extraction of blood; an arterial infusion catheter being configured to be inserted into the vicinity of an artery supplying blood to the brain; coupling means for establishing an first extra-corporeal blood circuit for cooled blood between said extraction catheter and said arterial infusion catheter via a pumping means and a temperature regulating device capable of cooling extracted blood;

Species QQ- In this embodiment a temperature sensor would be configured to adjusting the infusion rate of said cooled blood dependent on said sensed temperature for achieving a desired temperature in the brain; or to adjusting the temperature

of said cooled blood dependent on said sensed temperature for achieving a desired temperature in the brain.

Species WW- An embodiment of an equipment for brain hypothermia comprises, to enable a brain-selective hypothermia: a container with an infusion solution having a first temperature and an arterial infusion catheter connectable to an outlet of said container, said arterial infusion catheter having an infusion solution lumen; a distal end of said arterial infusion catheter being configured to be percutaneously inserted into an artery in the vicinity of a branch artery supplying blood to the brain;

Species VV- An embodiment of equipment for brain hypothermia comprises, to enable a maintained hypothermia: an extraction catheter configured to be inserted into a blood vessel for extraction of blood; an arterial infusion catheter configured to be inserted in an artery into the vicinity of an artery supplying blood to the brain; means for establishing an second extra-corporeal blood circuit for cooled blood between said extraction catheter and said arterial infusion catheter via a pumping means and a cooling device capable of cooling extracted blood;

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, no pending claim is considered generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims

are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roz Maiorino whose telephone number is 571- 272-4960. The examiner can normally be reached on 9am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4377. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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